EFESO CONSULTING
PHARMA & LABS PRACTICE

MANAGEMENT BRIEFING

UNLOCKING POTENTIAL IN YOUR REGULATORY AFFAIRS ORGANISATION

Applying Real Lean principles to free up capacity, increase quality and accelerate time to submission

BSM

The Global Regulatory Affairs function within any life-science company is not the same as a manufacturing or laboratory environment. While many of the key principles of traditional lean still apply, there are many unique challenges involved in effectively implementing them in Regulatory Affairs (RA).

The opportunity to apply lean in this environment is not intuitively obvious, as RA activities are project-based, with workloads and timelines which are both variable and unpredictable, and tasks with a hugely variable degree of complexity. Most improvement efforts focus on value stream mapping and targeting of point wastes within the process. They also typically involve the implementation of large scale IT systems which resolve certain issues in the short term but fail to address the underlying process problems.

BSM have developed methodologies and tools based on the *'Real Lean'* principles of levelling, flow and standard work that enable RA organisations to provide a better quality service and deliver exceptional improvements in productivity and lead-time. This applies to the full spectrum of regulatory activities from strategy and content development, the associated *'manage and build'* activities, through to operational activities such as publishing and archiving.

Benefits

- Defined, structured and controlled processes with clear ownership delivering more consistent and predictable performance.
- Freeing up of resources through levelling to allow greater focus on regulatory issues and content quality.
- A clearer understanding of capacity and resourcing requirements.
- Greater consistency across regions and TA's.
- Improved RFT, with reduced errors and rework.
- Improved work-life balance for employees.
- A culture of pro-active performance management and continuous improvement.

What we often find in Regulatory Affairs Processes

Most Regulatory Affairs groups manage to get important, urgent and complex information to the health authorities on-time, most of the time. However, this is typically achieved only via a constant level of "fire-fighting" driven by a number of underlying process and organisational issues.

Below is a summary of the type of issues, typically identified during a BSM assessment:

Workload

- Significant volatility in volume and mix of work associated with new product and lifecycle submissions.
- Unpredictable work content for individual submissions.
- Resourcing level dictated by workload peaks.
- Poor group level visibility of current and future activities.
- Impact to work life balance from high volumes of urgent requests.

Processes

- Lack of clear process step ownership or role definition.
- Variation in process from location to location and therapeutic area to therapeutic area.
- Delays throughout the process leading to a constant level of urgent requests.
- Poorly defined or no process for issue escalation.
- Less value placed on the logistical and execution elements of the process.

Quality

- Excessive reviews and rework cycles.
- "Right eventually" as opposed to "Right First Time" (RFT) approach.
- No measurement of key quality metrics.

Planning

- Dedication of resources by Product, Task, Therapeutic Area (TA) or region resulting in short interval volatility and imbalance in individual's workloads.
- Inconsistent application of project management / planning approaches to submissions.
- Too many "Planners" and multiple layers of planning.
- Most activities regarded as non-routine due to issues with urgency or quality.

Organization

- No overview of work assignment and progress.
- Difficult to identify performance issues.
- Management structure unsuitable for issue escalation.
- Significant use of outsourcing and contractors.
- Minimal flow of people between the different parts of the organization.
- People working as individuals as opposed to teams sharing workloads and resources.

Processes and Roles

The first step in a Real Lean implementation in RA is to assign activities to the appropriate people and ensure that they are executed in a consistent manner to a high standard of quality. Because of this, solution development first focuses on defining a single end-to-end process with clearly assigned roles and responsibilities, which can be consistently applied across all TA's and regions. The process itself should describe all activities from initiation to submission. It should be at a level of detail that can apply to the various types of submission that the organisation manages e.g. original applications, health authority responses, safety reporting, etc. In our experience three different types of role are required to support this process properly, each role has a particular focus and skill-set. These roles are typically described as 'Strategy', 'Content' and 'Operations'.

Strategy Role	Responsible for developing and driving the regulatory strategy for a product or a group of products.	Product knowledge essential	Process knowledge incidental
Content Role	Responsible for authoring regulatory content and ensuring consistency and quality in the inputs from other functional areas.	Product knowledge essential	Process knowledge helpful
Operations Role	Responsible for active project management of each submission. Coordination and execution of all logistical activities required to support health authorities.	Product knowledge helpful	Process knowledge essential

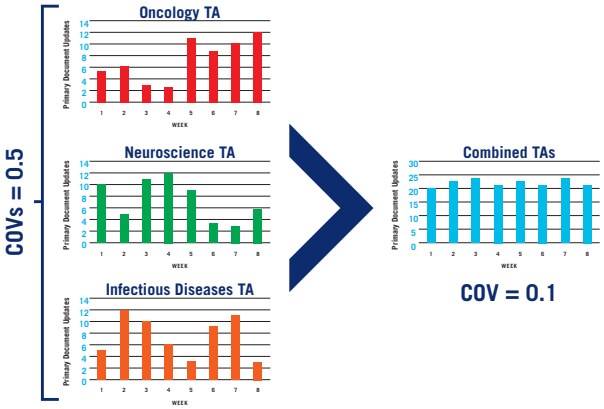
- Quality and accuracy within the process is critical. Right First Time (RFT) measures are incorporated at appropriate points, with routine reviews of these metrics to identify continuous improvement opportunities.
- Within the 'Operations Role' specific emphasis is placed on proactive project management at an individual submission level to ensure that all components are delivered on time. Potential issues are identified and addressed up front and the submission flows through the necessary 'Content Development' and 'Build and 'Publish' activities without any delays.
- In organisation design the Content and Operations Roles must work hand in hand.

Levelling, Flow, Standard Approaches and Visual Management

Levelling and Flow

Levelling and flow are key features of BSM solutions and address the huge opportunity of workload volatility losses. The most commonly applied levelling techniques in RA are Queue Based and Mixed Work Stream Levelling.

Figure 1. Levelling of workload for individuals and groups



Queue Based Levelling involves creating a flowed process in which submissions are moved through the entire sequence of activities quickly and without delays between steps. The difference between this "through-put" time and the available "lead-time" allows work to wait in a structured queue from which a level amount of work can be launched into the group on a daily or weekly basis.

Mixed Work Stream Levelling involves combining two or more volatile sources of work which share the same resources. The work streams to be combined are selected so that the combined workload is less volatile than the individual workloads. This approach is particularly relevant to levelling the workload for the Operations Role, where process rather than product knowledge is essential. This combined with reducing product specific dedication will result in a much more level workload for individuals and groups. See *Figure 1*.

Standard Approaches and Visual Management

There are a number of critical steps within the process that benefit from having a standard approach defined:

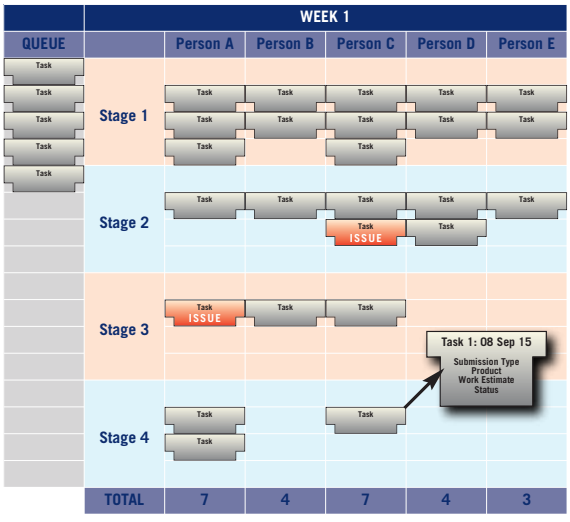
- **Triage:** In order to level workloads effectively it is necessary to understand the size and urgency of all tasks to be managed by the group. This is achieved through a standard 'Triage' step at the very beginning of the submission process, the details of which are described in a standard work Role Card.
- **Content development and review cycles:** The waste associated with excessive review loops (which typically occur because people are unsure as to exactly what should be done during each iteration) can be significantly reduced by defining best practice criteria for "what finished looks like" in each loop of content review.

Visual management is an approach to managing operations that uses visually presented information, signals and controls to direct activities, communicate progress and highlight issues.

Good visual management is critical to embedding and sustaining lean within regulatory affairs and indeed other environments. In a manufacturing or lab environment where staff are co-located visual management would typically involve a physical board at which everyone "huddles" on a daily basis. (Huddles are short, frequent stand-up team meetings at which progress is discussed and issues identified. They are the key means of interaction with the visual management system).

However regulatory groups are typically distributed geographically and so design of virtual tools for supporting huddle meetings is a key part of any project. An example of the key elements of such a system is detailed in *Figure 2*. In any RA project detailed documentation of requirements and selection of an appropriate IT tool are key project steps.

Figure 2. Visual management elements



BSM is the global leader in the provision of Real Lean transformation services to life science companies. We assist companies to deliver significant measureable improvement within their Regulatory Affairs and R&D processes. We develop innovative solutions via the application of best practice lean, re-engineering and change management techniques, and we have an extensive track record of successful implementations.

We are now part of EFESO Consulting, extending our global reach and our ability to provide local language support.

To discuss any aspect of this briefing or your own Regulatory Affairs organisation and opportunities for improvement please contact:

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